

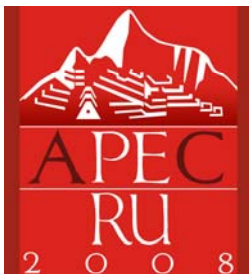


**Asia-Pacific
Economic Cooperation**

2008/SOM2/CD/010a
Agenda Item: 5

Chemical Assessment and Management Program (ChAMP)

Purpose: Information
Submitted by: United States



7th Chemical Dialogue Meeting
Arequipa, Peru
22 May 2008



Chemical Assessment and Management Program (ChAMP)

Office of Pollution Prevention and Toxics

**U.S. Environmental Protection Agency
May 16, 2008**

1



North American Cooperation on Chemical Management

- At Security and Prosperity Partnership (SPP) Summit in August 2007, President Bush, Canadian Prime Minister Stephen Harper and Mexican President Felipe Calderon committed to specific goals to:
 - Enhance regulatory cooperation among Canada, Mexico, U.S.
 - Accelerate and improve effectiveness of actions to safeguard health and environment
 - Provide cost-effectiveness for business and government
 - Retain national regulatory authority

2



SPP Commitments

- Regional Commitments
 - Canada & U.S. work with Mexico to establish a Mexican chemical inventory, Inventory updates, strengthened North American chemical regime
 - Research and development on new approaches to testing and assessment.
 - EPA and Canadians have begun collaborating
 - Create mechanisms to share domestic scientific information and best practices for chemical assessment and management. Coordinate approaches to develop international standards.
 - Enhance Mexico's capacity for chemical assessment and management
 - Reaffirmed: WSSD 2020 goal; Regional SAICM implementation

3



SPP Commitments

- National Commitments
 - U.S.: Assess and initiate needed action on 6,750 chemicals
 - Canada: Realize its Chemical Management Plan
 - Mexico: Establish a chemical inventory

4



Chemicals Assessment and Management Program (ChAMP)

- New title encompasses U.S. SPP commitments and possible enhancements to EPA's existing chemical program which include:
 - HPV Challenge-type program for high production volume "inorganic" chemicals
 - Resetting the TSCA Inventory

5



U.S. Commitments Under SPP

- By the end of 2012:
 - Assess and initiate needed action on the over 6,750* existing chemicals produced above 25,000 lbs/yr the U.S.
 - Includes High Production Volume (HPV) and Moderate Production Volume (MPV) chemicals
 - Builds off of prior efforts:
 - HPV Challenge
 - IUR Reporting
 - Canadian categorization, etc.
 - Make and publicly release screening level decisions and initiate needed action

*Based on preliminary statistics from 2006 IUR Data

6



Screening Decision Process – HPV Chemicals

- Assess and prioritize HPV chemicals (1 million lbs/yr) based on hazard/exposure information
 - HPV Challenge test data
 - IUR Exposure/use reporting
- Evaluate Risks
- Identify and initiate needed action, e.g.
 - Gather/generate needed information
 - Take control measures
 - Identify as current low priority
- Document and post assessments and conclusions on the web

7



HPV Challenge Program

- Voluntary program for companies to make basic hazard/fate data on their HPV chemicals publicly available by 2005
- Modeled after OECD HPV Screening Information Data Set (SIDS) Program
- Encouraged use of Structure Activity Relationships (SAR)/ Category Approaches

8



Inventory Update Reporting (IUR)

- Snapshot, every 5 years, of chemicals in commerce in the U.S.
- Manufacturers, including importers, report information on chemicals with site-specific production volumes of 25,000 pounds or more
- Processing and use information on organic chemicals with site-specific production volumes of 300,000 pounds or more
 - Mostly HPV Challenge chemicals
 - Processing and use reporting for inorganic chemicals begins in 2011 (next IUR)


9



Tools to Implement Risk-Based Prioritizations (RBPs)

- Where identified as low-concern at this time:
 - Document initial prioritization rationale and post to web
- Where additional info or action is needed, the options include:
 - Contact producers with request for info, informal action
 - Data from other offices, Agencies, Canada, OECD
 - TSCA §8(a) reporting rules (e.g., exposure, release data)
 - TSCA §5(a)(2) Significant New Use Rules (SNURs)
 - Engage with stakeholders (e.g. DfE, voluntary action, etc.)
 - TSCA §4 test rules
 - Develop/implement Challenge programs, other risk reduction actions
 - Initiate creation of TSCA §5(b)(4) list

10



Section §5(b)(4) “Risk List”

- Chemicals with risk concerns could be considered for Sec. 5(b)(4) risk list
 - Requires rulemaking and minimum of a “*may present an unreasonable risk*” finding;
 - may be possible with HPV and IUR data
 - Risk list approach could provide incentive for stewardship

11



Screening Decision Process – MPV Chemicals

- Developing approach to assess MPV Chemicals
 - Produced or imported at quantities $\geq 25,000$ lbs/yr and < 1 million lbs/yr.
 - Apply available data, Canadian categorization results, and EPA Structure Activity Relationships (SAR) analysis to assess hazard and fate.
 - Basic exposure/use data are available only for MPVs produced at $\geq 300,000$ lbs at a site
 - Use Hazard Characterizations (HCs) to identify MPVs that require follow-up, initiate actions
 - Gather additional data (exposure, testing, etc.)
 - Risk management
- Document and post assessments and conclusions on the web.

12



Meeting the SPP Goals

- 2007
 - Developed process for screening-level Hazard Characterizations (HCs) and Risk Characterizations (RCs), and Risk-Based Prioritizations (RBPs) on HPV chemicals
 - Posted over 150 HCs
- 2008
 - Posted additional 50 HCs in January
 - Posted initial set of 19 RBPs in March
 - Continue developing and posting RBPs
 - Post initial MPV HCs
- 2009
 - Continue posting RBPs for HPV chemicals and significantly ramp up posting MPV HCs

13



Program Enhancements – Inorganic HPV Challenge

- Inorganics first included on IUR in 2006; no exposure data reporting until 2011
 - EPA estimates that there are likely to be between 400 and 500 HPV inorganic chemicals reported
- EPA considering IHPV Challenge Program Mirroring HPV Challenge Design
 - Identify and work with stakeholders to develop program/process/timing.
 - Apply established EPA, OECD guidance to determine inorganics data needs
- Assess, prioritize, and initiate needed action on IHPV chemicals (2012-2014)

14

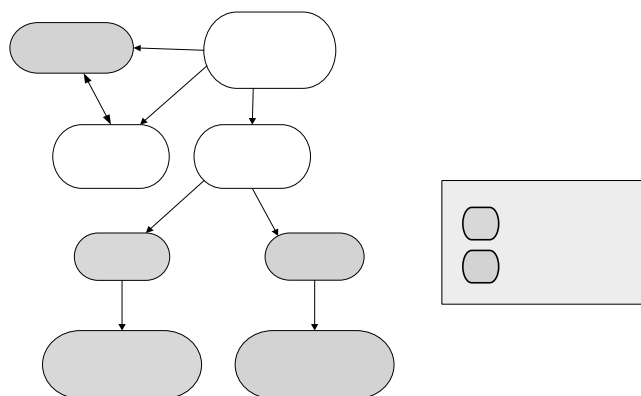


Program Enhancements – Resetting the TSCA Inventory

- TSCA §8(b) requires EPA to “compile, keep current, and publish” TSCA Inventory
- Inventory’s “83,000 chemicals” are misleading
 - Likely that many chemicals are no longer manufactured/imported; or
 - Are produced only in low or episodic volumes
- Such an effort would provide a more meaningful and usable resource that reflects the chemicals actually in commerce in the U.S.

15

Chemical Assessment and Management Program



16



Relationship to Work by the Commission on Environmental Cooperation

- CEC's Sound Management of Chemicals (SMOC) work group has worked for over a decade to deal with individual chemicals issue in North America
- SMOC is now focused on regional implementation of the Strategic Approach to International Chemicals Management (SAICM) in NA
- The SPP regional and national commitments provides another avenue to complement SMOC's efforts and realize progress

17

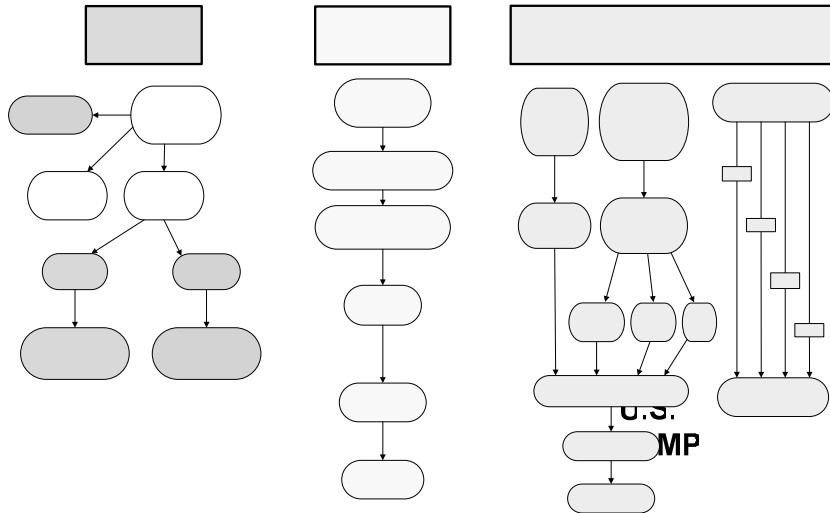


Timing of Actions Under SPP and Their Relationship to Timing Under REACH

- Parallel schedules for priority chemical assessments should allow U.S. and Canada to share/coordinate timing of data and assessments and follow-up action, where appropriate
- Because the REACH 1st registration deadline (HPV chemicals) is Dec. 2010 and the 1st authorization candidate list is expected in late 2008, REACH submitters and evaluators will benefit from U.S. and Canadian work
- REACH registration dossiers can meet future follow-up testing needs for U.S. HPVs/MPVs and IHPVs
- Schedule for completion of North American assessment work (2012) compares favorably to timing of REACH registration schedule (2010-2018)
- U.S. (EPA), Canada (Environment and Health Canada) and EC (DG Environment, DG Enterprise, and European Chemical Agency) officials met in December 2007 to begin consideration of future cooperation and staff exchange opportunities

18

Comparing U.S., Canada, and EU Approaches



Resetting
the Inventory

Current
TSCA
Inventory

20

2006

DSL
Categorization/
Prioritization

Non-IUR
Chemicals

IUR
Chemicals

2006

500 High
Priority Chemicals

Chemicals with
Identified Info Needs

Announce
Challenge

Substance
Profiles

Notice to
Obtain More
Info

Risk
Assessments

Risk
Management

2011


Environmental Protection Act Dom
he CMP are not shown on this fig

20

1,000 t = 2.2 M lbs.; 100 t = 220k lb

Stakeholder Engagement

- EPA seeking input from a wide range of partners and stakeholders
 - Series of meetings and discussions over March through June period
 - Focus meetings, webinars, pre-established conferences/meetings
 - Industry, NGOs, States and Tribes, Federal Partners
- EPA goal is to provide feedback to Administrator this summer and, as appropriate, begin implementing program enhancements



Chemical Assessment and Management Program: Input Welcome!

- o Comments can be submitted via the following ways:
 - o To submit comments via e-mail regarding the SPP efforts and possible enhancements, send to oppt.ncic@epa.gov; or
 - o Written comments to USEPA, CBIC, 1200 Pennsylvania Avenue, NW, Mail Code 7404, Room 6428, Washington, DC 20004. Please reference docket number EPA-HQ-OPPT- 2008-0319 when submitting comments.
- o For more information, please visit EPA's Chemical Assessment and Management Program (ChAMP) website: <http://www.epa.gov/champ/>